



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/651,846	08/31/2000	Timothy Hla	UCT-0012	4421

23413 7590 12/19/2003

CANTOR COLBURN, LLP
55 GRIFFIN ROAD SOUTH
BLOOMFIELD, CT 06002

EXAMINER

EPPS FORD, JANET L

ART UNIT	PAPER NUMBER
----------	--------------

1635

DATE MAILED: 12/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/651,846

Applicant(s)

HLA ET AL.

Examiner

Janet L. Epps-Ford, Ph.D.

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33-82 is/are pending in the application.
- 4a) Of the above claim(s) 41-53, 62-72 and 79-82 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33-40, 54-61 and 73-78 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9-22-03.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's Sequence Amendment filed 8-08-03 is technically sound and has been entered into the Sequence database of the USPTO-STIC division.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Arguments

3. Claims 33-40, 54-61 and 73-78 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the same reasons of record as set forth in the prior Office Action mailed 5-06-03.

Applicant's arguments filed 8-08-03, have been fully considered but they are not persuasive. Applicants traverse the instant rejection on the grounds that EDG-1 and EDG-3 receptors were published and well known in the art prior to filing of the instant application. Moreover, Applicants argue that since the specification now contains the DNA sequence listings for the EDG-1 and EDG-3 genes, it thus contains sufficient disclosure to enable one of ordinary skill in the art to practice the claimed invention as is required under 35 U.S.C. § 112. Based on the nucleotide sequences of human EDG-1 and EDG-3, Applicants argue that one could readily design an antisense oligonucleotide according to the present claims, therefore the rejection should be withdrawn for those reasons. However, contrary to Applicant's assertions, it is noted that written description requires that Applicants be in possession of the full scope of the claimed invention as of the filing date of the patent application. Applicants suggests that with the

Art Unit: 1635

knowledge of the EDG-1 and EDG-3 sequences one could readily make antisense targeting these sequences, however it is apparent that Applicant is suggesting that further experimentation be performed in order to isolate the claimed invention. As argued previously, there is a high level of unpredictability in the antisense art for design of functional antisense absent the sequence structure of the target sequence and knowledge of suitable regions that are open to binding by a particular antisense sequence. The claims are broadly drawn to an undefined genus of nucleic acid sequences, which might hybridize to an undefined genus of target EDG-1, or EDG-3 target genes. This breadth, coupled to the unpredictability in the art absent specific sequence information of the target gene and accessible regions and the lack of such teaching in the instant disclosure, leads one skilled in the art to the conclusion that Applicant was not in possession of the scope of the claimed invention at the time the invention was made. The claimed genus of compounds read on antisense targeting all polymorphic, allelic, and splice variants of nucleotide sequences encoding EDG-1 or EDG-3. However, the specification as filed does not teach by way of sequence target EDG-1 or EDG-3 gene from other whole organisms, accessible regions from such sequences for design of antisense, nor specific sequence structure of nucleic acid sequences which function as antisense and have the capability to bind and specifically inhibit a particular target EDG-1 or EDG-3 sequence.

See *Fiers v. Revel*, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993); wherein it was found that: An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. Accordingly, "an adequate written description of a

DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d. at 1606.

Therefore, a mere wish or plan to identify antisense oligonucleotides that function to bind and inhibit expression of EDG-1 or EDG-3 is not sufficient to establish that Applicant's invention was sufficiently reduced to practice such that Applicants had full possession of the claimed invention at the time of filing of the instant invention.

Conclusion

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Art Unit: 1635

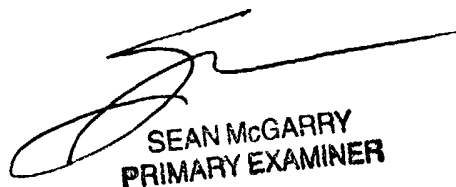
5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford, Ph.D. whose telephone number is 703-308-8883. The examiner can normally be reached on Monday-Thursday, 8:30 AM - 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on 703-308-0447. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Janet L. Epps-Ford, Ph.D.
Examiner
Art Unit 1635

JLE


SEAN MCGARRY
PRIMARY EXAMINER